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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,860

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Robert Douglas

3869/038 US

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22440 7590 02/22/2010  
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EXAMINER

MATTER, KRISTEN CLARETTE

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3771

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,860	<b>Applicant(s)</b> DOUGLAS ET AL.	
	<b>Examiner</b> KRISTEN C. MATTER	<b>Art Unit</b> 3771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/27/06 and 9/19/07</u> .                                     | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I, claim(s) 1-17, drawn to a CPAP apparatus and method of controlling that apparatus.**

**Group II, claim(s) 18, drawn to an apparatus and method for determining a mouth leak.**

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: It is submitted that controlling a CPAP blower with a pressure-time template and in synchrony with a patient's breathing cycle is the special technical feature of Group I and that flagging that a mouth leak has occurred when a leak volume during exhalation exceeds that during inhalation by a threshold is the special technical feature of Group II. Since Groups I and II do not share any of the special technical features identified, the application does not relate to a single inventive concept or one invention. In addition, search for the second invention will require an additional unwarranted search burden on the examiner.

During a telephone conversation with Michael Rackman on 2/17/2010 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-17.

Affirmation of this election must be made by applicant in replying to this Office action. Claim

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18 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Priority***

Examiner notices that priority to provisional applications 60533411 and 60545658 was properly claimed under 35 USC 119(e) in the oath submitted on 3/14/2207, but that the filing receipt indicated these applications as being foreign applications. Examiner has requested an updated filing receipt be mailed to applicant indicating applicant has not claimed foreign priority to these applications, only priority under 35 USC 119(e).

#### ***Specification***

The disclosure is objected to because of the following informalities: the specification should be updated to include all parent cases (i.e., 2 provisional applications and the PCT) in the related cases section on page 1.

Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation of “at least one sensor” in line 6. However, a pressure sensor and a flow sensor have already been claimed so it is somewhat confusing as to whether the "at least one sensor" is one of the above mentioned sensor or an additional sensor that has the sole function of determining transitions between inhalation and exhalation.

Claims 2-17 are dependent on rejected claim 1 and are therefore rejected for the same reasons outlined above with respect to claim 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Froehlich et al. (US 5,551,419, herein referred to as “Froehlich”) in view of Berthon-Jones (US 5,704,345).**

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Regarding claims 1 and 2, Froehlich discloses CPAP apparatus having a blower (12), a patient interface (11), an air delivery conduit (14), a pressure sensor (16), a flow sensor (15), an air synchrony module to determine transitions between inhalation and exhalation (see column 2, lines 60-65 and column 6, lines 15-20 for example), and a control mechanism (17) programmed to provide positive pressure in accordance with a predetermined pressure-time template (see Figure 4). Froehlich further discloses that a apparatus is controls blower operation by automatically determining the presence of sleep disordered breathing and automatically determining a treatment pressure in accordance with the presence of sleep disordered breathing (column 5, lines 35-55), setting at least one characterizing parameter of the pressure-time template to the treatment pressure (column 6, lines 15-27 and column 13, lines 20-30), and controlling the blower to delivery a supply air in accordance with the template and in synchrony with the patient's breathing cycles (via lines 19 and 20).

Froehlich discloses determining sleep disordered breathing, such as apnea, from “known techniques” but does not specifically mention an index. However, indexes are well known and commonly used in the art for determining the presence of a sleep disordered breathing event. In addition, Berthon-Jones discloses a similar CPAP apparatus that determines the presence of apneas by calculating an index (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an index for determining the presence of sleep disordered breathing in the system of Froehlich because it would have allowed a user to use a well known means for determining the presence and/or severity of sleep disordered breathing and to provide therapy as needed. Such a modification would involve the

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mere substitution of a well known method of determining apnea episodes in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claim 3, Froehlich discloses the template can be a square wave (see column 2, line 64).

Regarding claims 4 and 5, Froehlich discloses controlling IPAP and EPAP levels and incrementally increasing or decreasing those values in accordance with the detection of apneas (which would be considered a maximum or minimum value).

Regarding claim 6, Froehlich does not specifically mention setting the EEP in accordance with the detection of sleep disordered breathing. However, absent a critical teaching and/or showing of unexpected results from setting the EEP (as opposed to an average or max pressure for example), examiner contends that which part of the breathing signal curve is set by the controller in response to the detection of sleep disordered breathing is considered an obvious design consideration to one of ordinary skill in the art to increment/decrease any well known and commonly used part of the signal in order to provide effective treatment that is as comfortable as possible to a patient. Such a modification would appear to involve the mere substitution of a well known method in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art or at least have been obvious to try from an infinite possible range of choices (i.e., parameters of the breathing signal).

Regarding claims 7 and 8, the breathing signal is a wave that has both maximum and minimum values.

Regarding claim 9, Froehlich discloses CPAP pressure is generally delivered between 3-20 cm H<sub>2</sub>O, which overlaps the claimed pressure.

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Regarding claims 10 and 11, Froehlich does not specifically disclose a fixed-swing or keeping the swing small at lower pressures. However, absent a critical teaching and/or showing of unexpected results from having a fixed-swing, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a fixed-swing in order to prevent the swing from getting too large if a high number of sleep disorder breathing events was detected, to increase comfort to the patient by keeping the maximum and minimum pressure levels close to one another, and to allow the device to effectively get to the desired min/max pressure levels (i.e., if the swing is too large the system might not be able to reach the desired pressures in the given amount of time of the breathing cycle). In addition, the terms “small” and “low” are relative terms and since the pressures are generally between 3-20 cmH2O, examiner contends that any pressure swing can be considered to read on the claim language. Furthermore, there is nothing structurally that would prevent the use of fixed-swings and it appears as though the device would work equally well with a fixed-swing when increasing/decreasing the pressure.

Regarding claims 12-16, Froehlich discloses also controlling the blower in accordance with the detection of snoring (again which can be derived by an index as taught by Berthon-Jones). In addition, Berthon-Jones teaches an index indicative of flow flattening (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have also determined a flow flattening index as taught by Berthon-Jones in the device of Froehlich and to have set either or both of the EPAP and IPAP according to these various indexes in order to provide effective treatment to the patient at a minimal pressure as possible to increase comfort. Such a modification would appear to involve the mere substitution



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of a well known method of determining the presence of sleep disordered breathing (i.e., flow flattening) and a well known method for controlling a blower in response to such detection (i.e., setting both EPAP and IPAP) in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art of record.

Regarding claim 17, Froehlich does not specifically mention a look-up table. However, the controller is programmable and look-up tables and arrays are well known and commonly use processing techniques for creating signals. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have had the breathing signal be derived from a look-up table or array because it would have provided a well known means of creating a safe breathing profile for a user. Such a modification would appear to involve the mere substitution of a well known method in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/  
Examiner, Art Unit 3771